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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,406	01/22/2001	Michael S. Halpern	7933-38	5749

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EXAMINER
YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
1642	11

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,406	HALPERN ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The examiner of the application has changed. This case has now been transferred as of 7/2/02. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Christopher Yaen, Group Art Unit 1642.

Information Disclosure Statement

2. The Information Disclosure Statement filed 7/6/01 (paper no. 5) is acknowledged and considered. A signed copy of the IDS is attached hereto.

Election/Restrictions

3. Upon further review and consideration, group II will be rejoined with group I, therefore, claims 1-28 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

4. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "strong" in claim 1 is a relative term which renders the claim indefinite. The term "strong" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to how strong the promoter to drive expression of the transgene needs to be, correction and clarification is required.

6. In regard to claim 11 and dependent claims thereof, it is unclear as to the method being referred, because claim 11 depends from itself.

7. In regard to claim 18, it is unclear which method is being referred, because the claim from which it depends recites a product. Correction is required.

8. For the record, *"cognate"* is understood to mean a *"gene sequence that is evolutionarily and functionally related between species"*, as disclosed in the specification at page 9 lines 1-2.

9. In regard to claim 28, it is unclear as the meaning of the phrase *"at least transgene"*. It is believed by the examiner that the phrase is to recite *"at least one transgene"*. Clarification and correction are required.

10. Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *c-src527, v-src, and c-src* transgenes, does not reasonably provide enablement for any other transgenes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice and make the invention commensurate in scope with these claims.

OK

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one

of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The nature of the invention: The claimed invention is drawn to a cellular immunogen, a method of preparing the cellular immunogen, and a method of vaccination comprising the administration of the cellular immunogen, wherein the cellular immunogen comprises an allogeneic donor cell transfected with at least one transgene construct.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that cellular based vaccines are available and are in the process of development. On such example, (Reilly *et al* Cancer Res. 2000 July 1;60:3569-3576) demonstrates that cellular vaccines to HER-2/neu, a proto-oncogene, is available and that although promising effects are demonstrated in a mouse model, that additional work need to be performed in understand transgene

expression and its influence on tolerance. Further, Reilly *et al* disclose that work still needs to be done in order to determine vaccine efficacy.

The amount of direction or guidance present and the presence or absence of working examples: The specification does not teach how to make or use a cellular immunogen with any other transgene other than *c-src527, v-src, and c-src*. No working examples are provided for transgenes other than *c-src527, v-src, and c-src*.

The breadth of the claims and the quantity of experimentation needed: Given the broad range of the claims, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

11. Claims 19-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cellular immunogen and a method of preparing the cellular immunogen, does not reasonably provide enablement for a method of vaccinating a host against a disease with the cellular immunogen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The nature of the invention: The claimed invention is drawn to a method of vaccinating a host against a disease associated with over expression of a target proto-oncogene with a cellular immunogen.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that cellular immunogenic therapy has been successful in generating

antitumor immunity. One such example, Yoshizawa *et al* (Arch Immunol ther Exp (Warsz) 2001;49(5):337-43) disclose that although such antitumor immunity can be achieved with cellular immunogens, difficulties and limitations for treating tumors. Further, Evans *et al* (Q J Med 1999;92:299-307) disclose that at best a cancer vaccine can only be therapeutic and that protective effects as a prophylactic *"belongs in the realm of fiction"* (see page 303 last paragraph).

The amount of direction or guidance present and the presence or absence of working examples: The specification disclose examples for eliciting an immune response through the administration of a cellular immunogen. However, the specification does not teach how to use vaccines for a protective effect against cancer, nor does the specification provide any working examples of how one of skill in the art would create the effect of protective immunity.

The breadth of the claims and the quantity of experimentation needed: Given the broad range encompassed within the claims, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6365151. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to a cellular immunogen and a method of preparing a cellular immunogen that comprises identical components and steps.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1,2,4,8-9,11,13, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramsay GM *et al* (Proc Natl Acad Sci U S A 1990 Mar;87(6):2102-6). Claims 1,2,4,8-9,11,13, and 17-18, for the purposes of this rejection, have been interpreted as drawn to a cellular immunogen comprising a transgene, wherein the transgene comprises a retroviral DNA, the proto-oncogene is *myc*, and the cellular immunogen is a fibroblast, and to a method of

preparing the cellular immunogen. Ramsay GM *et al* disclose a fibroblast that has been transformed with a retroviral DNA encoding *myc*. Further, Ramsay GM *et al* disclose a technique for preparing a cellular immunogen by transfecting a fibroblast cell with a retroviral DNA encoding *myc*.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
July 15, 2002

Brenda Brumback
BRENDA BRUMBACK
PATENT EXAMINER